

Message Text

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FM SECSTATE WASHDC
TO AMEMBASSY TOKYO

UNCLAS STATE 135658

E.O. 11652: N/A

TAGS: ETRD, JA

SUBJECT: TRADE FACILITATION COMMITTEE CASE - CONCEPT INC.

1. SUMMARY: COMMERCE (USDOC) FORWARDING NEW CASE FOR TFC CONSIDERATION CONCERNING GOJ MINISTRY OF HEALTH AND WELFARE (MHW) REQUIREMENT OF RETESTING A PREVIOUSLY APPROVED PRODUCT FOLLOWING THE APPOINTMENT OF A NEW AGENT. THE MHW REQUIREMENT THAT A PRODUCT BE RETESTED IF A NEW FIRM IS EMPLOYED TO ACT AS IMPORTER IMPEDES AND DISCRIMINATES AGAINST THE INTRODUCTION BY THE U.S. MANUFACTURER OF THAT PRODUCT INTO JAPAN. END SUMMARY.

2. CONCEPT INC. (CONCEPT) INITIALLY CONTACTED USDOC BY LETTER ON APRIL 6 CONCERNING THIS PROBLEM; USDOC WAS SUBSEQUENTLY CONTACTED BY LETTER ON APRIL 18 ON CONCEPT'S UNCLASSIFIED

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BEHALF OF THE OFFICE OF SENATOR RICHARD STONE OF FLORIDA (SENDING COPIES OF CORRESPONDENCE). ON MAY 8 CONCEPT PROVIDED ADDITIONAL INFORMATION OF PHONE BASED ON A LATE APRIL VISIT TO TOKYO BY CONCEPT'S INTERNATIONAL MARKETING MANAGER FOR CONSULTATIONS WITH THE FIRM'S NEW AGENT. ALL FACTS IN THIS CASE CONTAINED THIS CABLE.

3. TEXT OF TFC CASE ON BEHALF OF CONCEPT INC. TO BE PRESENTED TO GOJ ALONG FOLLOWING LINES:

A. SUMMARY OF CASE: CONCEPT INC. (CONCEPT) IS A U.S. MANUFACTURER AND EXPORTER OF MEDICAL EQUIPMENT TO JAPAN. THE MINISTRY OF HEALTH AND WELFARE (MHW) REQUIREMENT THAT THE FIRM'S PRODUCT, "PRESSURE VEIL" -- A DISPOSABLE BLOOD PRESSURE MONITORING DEVICE, BE RETESTED AND RE-INSPECTED FOLLOWING APPOINTMENT OF A NEW JAPANESE AGENT WILL FURTHER DELAY INTRODUCTION OF THIS PRODUCT IN JAPAN.

B. FACTS OF THE CASE: CONCEPT, A FLORIDA-BASED MANUFACTURER OF MEDICAL AND HEALTH CARE EQUIPMENT, HAS BEEN SUCCESSFULLY MARKETING ITS LINE OF EQUIPMENT, INSTRUMENTS AND SUPPLIES IN JAPAN THROUGH SEVERAL AGENTS AND DISTRIBUTORS FOR ABOUT EIGHT YEARS. IN JANUARY 1975 CONCEPT APPOINTED AMERICAN COMMERCIAL CO. OF TOKYO (AMCO) AS ITS EXCLUSIVE AGENT IN JAPAN FOR THE SALES OF ITS "PRESSURE VEIL" DISPOSABLE BLOOD PRESSURE MONITORING DEVICE, USED IN ANAESTHESIOLOGY. IN ACCORDANCE WITH THE PHARMACEUTICAL AFFAIRS LAW (PAL) OF 1960, AS AMENDED, AMCO APPLIED THROUGH THE PHARMACEUTICAL SANITATION SECTION OF THE TOKYO MUNICIPAL GOVERNMENT'S BUREAU OF PUBLIC HEALTH FOR THE NECESSARY PRODUCT APPROVAL AND APPROVAL TO ACT AS IMPORTER AND DISTRIBUTOR OF THE PRODUCT. ALTHOUGH PROCESSING OF THE APPLICATION FOR APPROVAL BEGAN IN EARLY

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1975, IT WAS NECESSARY TO REINITIATE TESTING JUNE 1975 FOLLOWING CHANGES IN PRODUCT PACKAGING. AMCO RECEIVED APPROVAL FOR THE IMPORTATION AND DISTRIBUTION OF THE PRODUCT FROM THE EVALUATION AND REGISTRATION DIVISION, PHARMACEUTICAL AFFAIRS BUREAU, MINISTRY OF HEALTH AND WELFARE, AND IN MAY 1977, APPROVAL OF "PRESSURE VEIL" WAS GRANTED BY THE MINISTRY. AMCO'S AGENCY WAS TERMINATED BY MUTUAL AGREEMENT IN JULY 1977 FOR BUSINESS REASONS.

CONCEPT HAS SUBSEQUENTLY APPOINTED KESEI MEDICAL INDUSTRIAL CO., LTD., OF TOKYO AS ITS NEW EXCLUSIVE AGENT. KESEI WAS ADVISED BY THE TOKYO MUNICIPAL BUREAU OF PUBLIC HEALTH THAT THE PRODUCT WOULD HAVE TO BE RETESTED IN CONNECTION WITH OBTAINING THE NECESSARY APPROVALS TO IMPORT AND DISTRIBUTE THE PRODUCT, ALTHOUGH PRESSURE VEIL HAD ALREADY UNDERGONE THE NECESSARY CLINICAL TESTING AND DESIGN INSPECTION PRIOR TO GRANTING THE APPROVAL TO AMCO IN MAY 1977. CONCEPT IS PROVIDING KESEI WITH THE NECESSARY DESIGN AND TECHNICAL DATA, AND PRODUCT SAMPLES TO INITIATE THE REQUIRED RETESTING. THE

REQUIREMENT TO RETEST THE SAME PRODUCT WILL FURTHER DELAY
CONCEPT'S INTRODUCTION OF THE PRODUCT IN JAPAN.

C. OISCUSSION; THE MHW REQUIREMENT THAT A PRODUCT
PREVIOUSLY APPROVED MUST BE RETESTED UPON THE APPOINTMENT
OF A NEW AGENT IS CLEARLY A BURDENSOME IMPEDIMENT TO THE
INTRODUCTION OF THAT PRODUCT INTO JAPAN. "PRESSURE VEIL"
IS CURRENTLY IN WIDESPREAD USE IN THE UNITED STATES AND
IN OTHER DEVELOPED COUNTRIES. IT WAS TESTED AND APPROVED
BY THE MHW A YEAR AGO. IT IS THE USG UNDER-
STANDING THAT UNDER GOJ/MHW APPROVAL PROCEDURES, ONCE
TESTING IS COMPLETE AND APPROVAL OF A PRODUCT HAS BEEN
GRANTED, THE APPOINTMENT OF A NEW IMPORT AGENT WOULD
REQUIRE NEW APPROVAL, BUT NOT RETESTING OF THE PRODUCT.
THE MHW REQUIREMENT THAT "PRESSURE VEIL" MUST BE RETESTED
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APPEARS, THEREFORE, TO BE INCONSISTENT WITH MHW
PROCEDURES AND THUS IS DISCRIMINATORY AGAINST THE INTRO-
DUCTION OF THE PRODUCT INTO JAPAN.

D. RELIEF SOUGHT: THE U.S. GOVERNMENT REQUESTS ON BEHALF
OF CONCEPT THAT THE MHW ACCEPT THE RESULTS OF THE PREVIOUS
TESTS OF "PRESSURE VEIL" CONDUCTED IN CONNECTION WITH THE
GRANTING OF APPROVAL OF THE PRODUCT IN MAY 1977, AND THAT
APPROVAL OF KESEI MEDICAL INDUSTRIAL EQUIPMENT CO.,
LTD., TO IMPORT AND DISTRIBUTE "PRESSURE VEIL" BE
EXPEDITED. (END TEXT)

4. EMBASSY MAY USE FOLLOWING TALKING POINTS IN
DISCUSSION OF CASE WITH MHW AND JAPANESE TFC OFFICIALS:
1) WHILE THE LAW GIVES CONSIDERABLE DISCRETION TO MHW
OFFICIALS WITH RESPECT TO THE TESTING AND APPROVAL
PROCEDURES, USDOC'S UNDERSTANDING OF THE TESTING, INSPEC-
TION AND APPROVAL PROCEDURES WERE OBTAINED FROM OFFICIALS
OF THE MHW IN CONNECTION WITH THE PREPARATION OF THE JAPAN
SECTORAL SURVEY IN EARLY 1978; 2) SAMPLES OF THE PRODUCT
AND TECHNICAL DATA ARE IN THE HANDS OF A NUMBER OF PRIVATE
INDIVIDUALS IN JAPAN AS A RESULT OF THE TESTING PROCEDURE.
THERE IS CONCERN, THEREFORE, THAT ANY DELAY RESULTING FROM
THE LENGTHY AND DUPLICATORY TESTING AND APPROVAL PROCESS
WILL PROVIDE AN OPPORTUNITY FOR THE DEVELOPMENT OF
COMPETITIVE PRODUCTS IN JAPAN WHICH WILL HAVE A NEGATIVE
IMPACT ON CONCEPT'S POTENTIAL MARKET SHARE; 3) WE WOULD
HOPE THAT ITS APPROVAL AS IMPORTER OF "PRESSURE VEIL"
CAN BE EXPEDITED SINCE KESEI IS A WELL ESTABLISHED,
SPECIALIZED MEDICAL EQUIPMENT IMPORTER.

5. CONCEPT SUGGESTS THAT EMBASSY CONTACT ITS EMPLOYEE
IN JAPAN, MR. YOSHIYA SEKIMOTO, P. O. BOX 17, HIGASHI

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MURAYA,A, TOKYO, PHONE: 91-94953, AND ALSO MR. TSUYOSHI
UETAKE, KESEI MEDICAL INDUSTRIAL CO., LTD., 19-6, 3CHOME,

HONGO, BUNKYO-KU, YOKYO, PHONE: 03-816-2811. THEY MAY
BE ABLE TO PROVIDE ADDITIONAL BACKGROUND FOR USE IN
EMBASSY'S PRESENTATION OF CASE TO GOJ OFFICIALS.

6. ACTION REQUIRED: EMBASSY IS REQUESTED TO SUBMIT CASE
TO TFC UNLESS EMBASSY AWARE OF INFORMATION CONTRARY TO
FACTS AS PRESENTED. VANCE

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*** Current Handling Restrictions *** n/a

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